

Outcomes of Restorelle® DirectFix Anterior Mesh in Pelvic Organ Prolapse

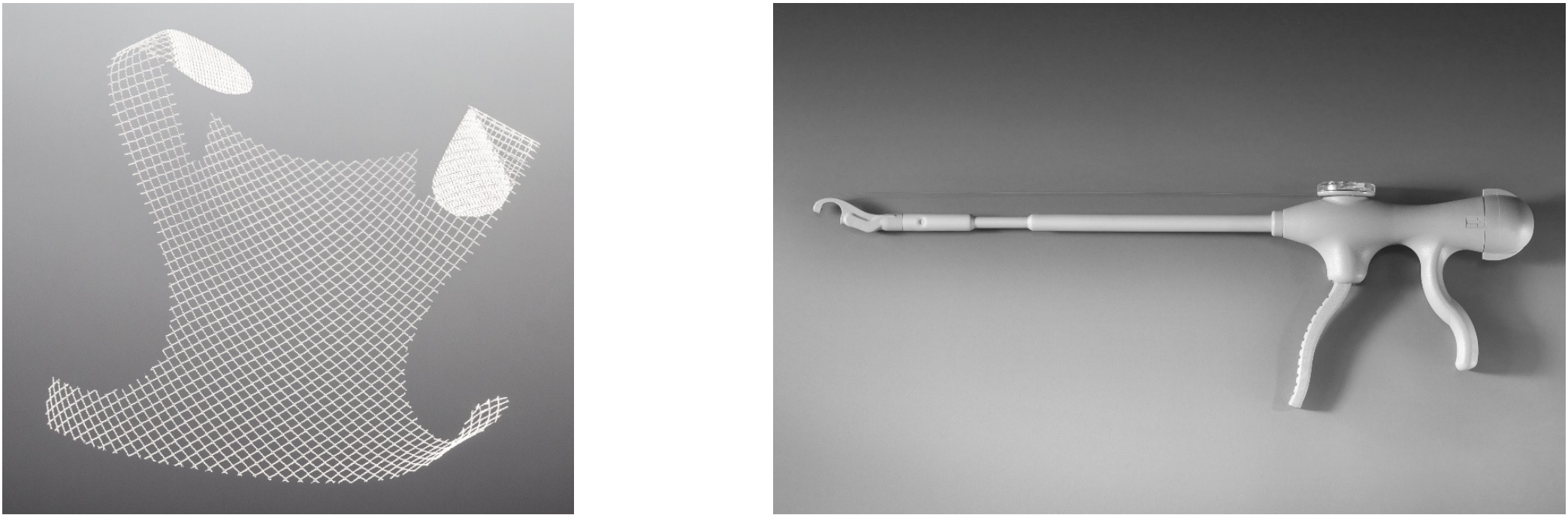
Yi Man Goh¹, Hong Liang Chua², How Chuan Han³, Jill Cheng Sim Lee²

- 1.Yong Loo Lin School of Medicine, Singapore
2.Department of Urogynaecology, KK Women’s and Children’s Hospital, Singapore
3.Mount Elizabeth Novena Hospital, Singapore

Introduction

- The use of transvaginal mesh surgery (TVM) in pelvic organ prolapse has resulted in lower prolapse recurrence than native tissue repair (NTR).
- However, insufficient safety and efficacy evidence led to the FDA withdrawal of TVMs in 2019.

The Restorelle DirectFix Anterior Mesh is a 4-arm, ultra-lightweight (19g/m²), type 1 polypropylene mesh for transvaginal anterior compartment repairs.



Aims

To determine the efficacy and long-term outcomes for the transvaginal Restorelle DirectFix Anterior Mesh in patients with severe pelvic organ prolapse (POP).

Methods

- This case series study was conducted in patients with severe pelvic organ prolapse who underwent Restorelle® TVM between 1 July 2017 and 30 September 2018 in KK Women’s and Children’s Hospital.
- The first 30 patients treated with the Reastorelle ® mesh were excluded from this study as part of the learning curve.
- Clinical characteristics and outcomes were identified through review of case notes, until 3 years post-operatively
- Primary outcome was defined as a patient with post-operative Baden-Walker Grade 1 or less cystocele while the secondary outcome was to assess for mesh-related complications.

Results

63 patients were enrolled. Table 1 shows the demographic profile of this cohort while Tables 2 and 3 show the pre-operative history and examination findings respectively. All 63 patients treated with Restorelle® DirectFix Anterior had concomitant gynaecological surgery.

Of the 63 patients, 43 followed up to 3-years post op. The surgical and peri-operative outcomes are summarized in Table 4.

Parameters	N = 63
Age (years), mean ± SD (range)	66.1 ± 7.3 (50-81)
Body mass index (kg/m²), mean ± SD (range)	25.0 ± 3.2 (18.6-32.6)
Sexually active, n (%)	10 (15.9)
Parity, mean ± SD (range)	
Normal vaginal delivery, n (%)	60 (95.2)
a) 1-3	49 (77.7)
b) >3	11 (17.5)
Forceps/vacuum delivery, n (%)	
a) 0	59 (93.7)
b) 1	3 (4.8)
c) 2	1 (1.6)
Lower section caesarian section only, n (%)	0
Menopause, n (%)	60 (95.2)
Hormone replacement therapy, n (%)	3 (4.8)

Table 1: Demographics of patients treated with Restorelle® DirectFix Anterior between July 2017 and September 2018

Parameters	N = 63
Signs and symptoms, surgical history	
Urinary frequency/nocturia, n (%)	38 (60.3)
Stress urinary incontinence, n (%)	24 (38.1)
Urinary urgency, n (%)	30 (47.6)
Urge urinary incontinence, n (%)	27 (42.9)
Fecal incontinence, n (%)	1 (1.6)
Lump at introitus, n (%)	62 (98.4)
Lump at introitus (months) (n=62), mean ± SD (range)	36.8 ± 48.0 (1 – 240)
Voiding difficulty, n (%)	27 (42.9)
Dyspareunia, n (%)	16 (25.4)
Previous gynecological surgery, n (%)	18 (28.6)
Pre-operative examination findings	
Stress Test Positive, n (%)	4 (6.3)
Cystocele, n (%)	
(a) Grade 3	41 (65.1)
(b) Grade 4	22 (34.9)
U/S Kidney, n (%)	
(a) Normal	42 (66.6)
(b) Hydronephrosis/ Hydroureteronephrosis	4 (6.3)

Table 2: Symptoms, surgical history and pre-operative examination findings of patients treated with Restorelle® DirectFix Anterior between July 2017 and September 2018

Parameters	N = 63
Anaesthesia, n (%)	
a) General	45 (71.4)
b) Regional	18 (28.6)
Duration of surgery (min), mean ± SD (range)	119 ± 27 (56 – 200)
Concomitant surgery, n (%)	
a) Vaginal hysterectomy	51 (81.0)
b) Anterior pelvic floor repair	6 (9.5)
c) Posterior pelvic floor repair	62 (98.4)
d) Sacrospinous ligament fixation	50 (79.4)
e) Mid-urethral sling	27 (42.9)
i. Altis	10 (15.9)
ii. Solyx	2 (3.2)
iii.TVT-Abbrevo	1 (1.6)
iv.TVT-Exact	14 (22.2)
f) Cystoscopy	63 (100.0)
Estimated blood loss (ml), mean ± SD (range)	257 ± 149 (50 – 800)
Intraoperative complications, n (%)	
a) Excessive blood loss > 500ml	4 (6.3)
b) Blood transfusion	6 (9.5)
i. 1 unit	5 (7.9)
ii. 2 units	1 (1.6)
c) Bladder perforation	2 (3.2)
d) Rectal perforation	1 (1.6)
e) Conversion to open hysterectomy	0
Hospital stay (day), mean ± SD (range)	5.2 ± 2.1 (2 – 15)
Catheterization (day), mean ± SD (range)	6.1 ± 7.7 (2 – 34)
Fever, n (%)	24 (38.1)
a) 1 day duration	11 (17.5)
b) 2 days duration	5 (7.9)
c) 3 days duration	5 (7.9)
d) >3 days duration	3 (4.8)
Postoperative complications, n (%)	12 (27.9)
a) Urinary tract infection	2 (3.2)
b) Thigh discomfort	0
c) Buttock pain	4 (6.3)
d) Voiding difficulty	6 (9.5)
e) Vaginal vault hematoma	2 (3.2)
f) Others*	6 (9.5)

Table 4: Surgical and peri-operative outcomes of patients treated with Restorelle® DirectFix Anterior between July 2017 and September 2018

**Other postoperative complications include medical complications such as anaemia, acute respiratory alkalosis, shingles, Type 2 myocardial infarction and hyponatremia*

Parameters	1 year (n = 63)	2 year (n = 49)	3 year (n = 43)
Abnormal urine flow	1 (1.6)	2 (4.1)	0
De novo SUI, n (%)	2 (3.2)	3 (6.1)	2 (4.7)
De novo U/UI, n (%)	1 (1.6)	3 (6.1)	0
Wound dehiscence, n (%)	0	0	0
Mesh extrusion	5 (7.9)	2 (4.1)	2 (4.7)
Dyspareunia, n (%)	1 (1.4)	1 (2.0)	0
Lump	0	1 (2.0)	1 (2.3)
Pelvic pain, n (%)	1 (1.6)	1 (2.0)	0
Recurrent cystocele, n (%)	1 (1.6)	1 (2.0)	1 (2.3)
a) Grade 2	1	1	1
Recurrent rectocele, n (%)	0	2 (4.1)	1 (2.3)
a) Grade 2		2	1
Recurrent vault prolapse, n (%)	0	0	0
Reoperation, n (%)	1 (1.6)	1 (1.4)	0
a) Mesh tightening	1	0	
b) Mesh excision	0	1	
Satisfaction, n (%)	63 (100)	49 (100)	43 (100)
Subjective cure rate, n (%)	63 (100)	48 (98.0)	42 (97.6)
Objective cure rate, n (%)	62 (98.4)	46 (93.9)	41 (95.3)

Table 5: Post-surgical outcomes of patients treated with Restorelle® DirectFix Anterior between July 2017 and September 2018.

At 36 months post-operatively,

- The subjective and objective cure rate is 97.6% and 95.3% respectively
- 2 (4.7%) patients developed new asymptomatic mesh erosion at 36 months, bringing the total to 9 (14.2%)**
- Only 1 patient required reoperation at 1 month due to mesh loosening.
- 1 patient underwent mesh excision in the 2nd postoperative year

Discussion

- Our study had a high follow up rate of 68.2% for three years postoperatively, which allow us to evaluate long-term surgical outcomes of the Restorelle mesh without loss to follow up bias
- However, all patients had concomitant surgeries done besides anterior repair and mesh insertion, which may confound the results.
- Other limitations include the observer bias in recurrent prolapse grading post-operatively

Conclusion

Despite high objective and subjective cure rates, patients who underwent the Restorelle DirectFix Anterior mesh had significant rates of mesh extrusion. Patients who are being considered for transvaginal mesh-augmented cystocele repairs need to be explicitly counselled pre-operatively about this risk. This case series highlights the need for long-term follow up and data reporting for patients undergoing new, novel treatments.